

REMARKS

In the Claims

Claims 21, 23, 26, 28-29, 32 and 34-35 were the subject of the Office Action dated September 1, 2009.

Claim 25 is combined into Claim 21. As such, Claim 25 is cancelled without prejudice.

Accordingly, Claims 21, 23, 24, 26, 28, 29, 32, 34 and 35 are now presented for further consideration.

Claims 21, 23, 24, 26, 28, 29, 34 and 35 are currently amended.

Detailed Response

1. Applicants wish to thank the Examiner for entering the claim amendments filed with the RCE on June 19, 2009 and for examining claims 21, 23-26, 28-29, 32 and 34-35.

2 and 3. Claims 21, 23-26, 28-29, 32 and 34-35 stand rejected as lacking adequate written description under 35 USC §112, first paragraph. The applicant respectfully traverses this rejection in view of the amended claims submitted herewith. Specifically:

Currently amended claim 21 recites the term "introducing orally" and deletes the term, "one or more specific needs."

Currently amended claims 34 and 35 delete the term, "one or more specific needs."

Claim 25 is deleted.

Currently amended claim 29 deletes the term, "solution."

Currently amended claim 34 deletes the term "or" and is amended to include the term, "is at least one polysaccharide selected from the group consisting of: galactomannans and glucomannans."

Currently amended claim 28 includes the term, "are surrounded by and aqueous envelope in at least some portion of a human's or animal's digestive tract."

Currently amended claim 21 includes the terms, "wherein the granular particles each comprise a plurality of polysaccharide molecules form a lattice structure having interstices and the active substances are bound with the interstices of the lattice structure," and "introducing orally the granular particles". Claim 24 depends from claim 21 and thereby incorporates the terms of claim 21; claim 25 is cancelled.

In view of the amendments made to the claims and in consideration of the foregoing remarks, withdraw of the rejection under 35 U.S.C. section 112 second paragraph is respectfully requested.

4 and 5. Claims 21, 23-26, 28-29, 32 and 34-35, stand rejected under 35 U.S.C. section 103(a) as being unpatentable over Shibata (EP 835654).

Page 3, lines 18-20 of Shibata only mentions the possibility of two active ingredients, Shibata fails to teach anything about using polysaccharide to form granular particle that separate two active substances from one another, the advantages of doing so or the methods for doing the same.

Moreover, Shibata states that, "it is possible to combine, two or more", teaching that different ingredients can be mixed together in its formulation not kept separate from one another as disclosed by the applicants. Far from making the applicants invention obvious, Shibata teaches away from the applicant's invention.

In consideration of the amendments made to the claims and the foregoing, the withdrawal of this obviousness rejection is respectfully requested.

6. Claims 21-26, 28-29, 32 and 34-35 stand rejected under 35 U.S.C. 103(a) as being unpatentable over Shibata (EP 835654 A1) in view of Walter (GB 2257358 A) or vice versa. Page 6 of the Action states that, "Shibata does not specifically disclose providing first and second composition, although the reference suggests that more than one active ingredient can be included in the composition." As discussed in the above Shibata does not teach that granules comprised in part of polysaccharides can be used to separate different active substances from one another, in fact the disclosure of Shibata teaches different ingredients can be mixed together. Accordingly, Shibata teaches away from the applicants' invention.

As discussed in some detail in an earlier office action dated October 23, 2008, Walter teaches formulations designed to protect active ingredients from harsh condition encountered under industrial process conditions, not formulations or methods of making the same for the segregation of active compounds from one another and the release of the same under physiological conditions. It is clear that Walter teaches mixing of the active substances prior to mixture with the polysaccharide (unlike what is advantageously claimed according to

embodiments of the subject invention). For example, the following Examples of Walter read as follows:

Example 2 states, "Enzymes or enzyme mixtures are mixed into...flour and sprayed..."

Example 3 states, "...enzymes or enzyme mixtures are embedded in a polysaccharide... Enzymes or enzyme mixtures are mixed into...flour and sprayed into a mixer together..."

Example 4 states, "Enzymes or enzyme mixtures are incorporated in oil and emulsified with...flour solution in the emulsifier and sprayed into fine guar flour with mixing..."

Example 6 states, "Enzymes or enzyme mixtures are homogenized in guar endosperm flour in a mixer."

Example 7 states, "...flour is mixed in the mixer with the calculated amounts of coenzyme powder and enzyme powder protected by embedding in nonionic polysaccharides... [from] ...Heat and pressure applications ..."

Example 8 states that it is similar to Example 7 but that "flours are used in conjunction with proteins and nutrient fibers and combined with, for example, vegetable, fruit, meat, and fish powder."

It is clear that there is no prevention of interaction between active substances being addressed or even suggested by the cited reference. The only problem being addressed is inactivation of enzymes and the like during industrial processing. Hence, mixing of active ingredients prior to processing with polysaccharides was perfectly acceptable according to the cited reference. The active ingredients are mixed in the first step and are then embedded in a second step. The premixing of the active ingredients taught by Walters and clearly consistent with the teaching of Shibata would obviate the applicant's invention.

In so far as combining Shibata and Walters, it would not have been obvious to one of ordinary skill in the art as Shibata teaches away from formulating active ingredients in a manner that prevents them from interacting with each other and their controlled release into the blood stream of a human or animal. Accordingly, the differences in the manufacturing processes and the implications for the subsequent uses of the granules as claimed by the applicants were simply not in, or apparent from, or obvious derivatives or combination of the cited art.

In consideration of the amendments made to the claims and the foregoing, the withdrawal of this obviousness rejection is respectfully requested.

Conclusion


In view of the amended claims and remarks submitted herewith, the applicants respectfully request that claims 21, 23, 24, 26, 28, 29, 32, 34 and 35 be found in condition for allowance and the action be taken to that end.

Applicants have so filed a petition for a one month an extension of time, filed along with the request fee. If any additional fees are due, the Office is hereby authorized to charge these to Deposit Account No. 02-0385, Baker & Daniels LLP, but not to include any issue fees.

Should the Examiner have any questions regarding any of the above, the Examiner is respectfully requested to telephone the undersigned at 317-237-1149.

Respectfully submitted,

By:



John J. Emanuele, Jr.

Reg. No. 51,653

BAKER & DANIELS

300 N. Meridian Street, Suite 2700

Indianapolis, Indiana 46204

Telephone: (317) 237-1149

Fax: (317) 237-1000